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10/748,449

12/30/2003

Richard D. Keeven

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MAGINOT, MOORE & BECK, LLP

CHASE TOWER

111 MONUMENT CIRCLE

SUITE 3250

INDIANAPOLIS, IN 46204

EXAMINER

WOODALL, NICHOLAS W

ART UNIT

PAPER NUMBER

3775

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/748,449 | Applicant(s) KEEVEN ET AL. | |
| | Examiner Nicholas Woodall | Art Unit 3775 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to applicant's amendment received on September 9th, 2009.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 24-43 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. For example, in claim 24 lines 3-4, the applicant positively recites part of a human body, i.e. "...that defines a femur facing side and a tibia facing side...". All the independent and dependent claims include these limitations, thus claims 24-43 include a part of a human body within their scope and are non-statutory. The examiner believes the claims should state something along the lines ...that defines a side configured to face a femur and a side configured to face a tibia... and will be interpreted as such for examination purposes. The applicant argues that the claims do not positively recite part of a human body since the terms are being used as adjectives and modifiers. However, this argument is not persuasive to the examiner because the element having to include a femur facing side or a tibia facing side requires the presence of a femur or tibia for the sides to face and therefore includes the femur or tibia within the scope of the claims. Therefore, the claims do positively recite a part of a human body and are non-statutory.

A claim directed to or including within its scope a part of a human body is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited,

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but exclusive property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 24, 33, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaufman (U.S. Patent 4,721,104).

Kaufman discloses a device comprising an instrument, an augment (5), and a femoral resection guide (60). The instrument includes a positioning member (61) defining a femur facing side and a planar tibia facing side. The positioning member includes a first coupler (65) and a connector member comprising a first mating feature (a bore receiving or created by screw 62; column 5 lines 1-7). The augment includes an upper surface, a contoured lower surface, and a second coupler (92) that cooperates with the coupler to fix the augment to the positioning member, wherein the upper surface of the augment abuts the tibia facing side of the positioning member. The femoral resection guide includes a second mating feature (62) that mates with the first mating feature.

6. Claims 28 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by LaSalle (U.S. Patent 5,976,147).

LaSalle discloses a device comprising an instrument (12 and 18), an augment (20), and an intramedullary pin (16). The instrument includes a positioning member (18) defining a femur facing side and a tibia facing side, wherein the instrument includes a first coupler (elements 88, 90, 92, 94, etc.; see Figure 6) defining a pin like structure, a guide slot (the bore in the middle of element 12 that receives element 16) that receives the intramedullary pin, a handle extending from the positioning member (column 6 lines 33-36). The augment includes a second coupler (124) defining a bore that cooperates with the first coupler to fix the augment to the positioning member (see column 7 lines 15-24).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman (U.S. Patent 4,721,104) in view of Vito (U.S. Patent 5,931,838).

Kaufman discloses the invention as claimed except for the first coupler being a bore and the second coupler being a pin received within the bore, wherein the bore defines an internal groove that receives an o-ring engaging the pin.

Regarding the first coupler being a bore and the second coupler being a pin, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Kaufman wherein the first coupler is a bore and the

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second couple is a pin received within the bore, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

Regarding the bore defining an internal groove that receives an o-ring engaging the pin, Vito teaches a device comprising a first coupler (27) defining an internal groove (28) that includes a resilient o-ring (30) and a second coupler (40) that engages the o-ring in order to lock the two elements together. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Kaufman as modified above wherein the first coupler further includes an internal groove receiving a resilient o-ring that engages the second coupler in view of Vito in order to lock the two elements together.

9. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman (U.S. Patent 4,721,104).

Kaufman discloses the invention as claimed except for the first coupler being a bore and the second coupler being a pin received within the bore. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Kaufman wherein the first coupler is a bore and the second couple is a pin received within the bore, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

10. Claims 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman (U.S. Patent 4,721,104) in view of Vito (U.S. Patent 5,931,838).

Kaufman discloses a device comprising an instrument, an augment (5), and a femoral resection guide (60). The instrument includes a positioning member (61) defining a femur facing side and a planar tibia facing side. The positioning member includes a first coupler (65) and a connector member comprising a first mating feature (a bore receiving or created by screw 62; column 5 lines 1-7). The augment includes an upper surface, a contoured lower surface, and a second coupler (92) that cooperates with the coupler to fix the augment to the positioning member, wherein the upper surface of the augment abuts the tibia facing side of the positioning member. The femoral resection guide includes a second mating feature (62) that mates with the first mating feature. Kaufman discloses the invention as claimed except for the first coupler being a bore and the second coupler being a pin received within the bore, wherein the bore defines an internal groove that receives an o-ring engaging the pin.

Regarding the first coupler being a bore and the second coupler being a pin, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Kaufman wherein the first coupler is a bore and the second couple is a pin received within the bore, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

Regarding the bore defining an internal groove that receives an o-ring engaging the pin, Vito teaches a device comprising a first coupler (27) defining an internal groove (28) that includes a resilient o-ring (30) and a second coupler (40) that engages the o-ring in order to lock the two elements together. It would have been obvious to one

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having ordinary skill in the art at the time the invention was made to provide the device of Kaufman as modified above wherein the first coupler further includes an internal groove receiving a resilient o-ring that engages the second coupler in view of Vito in order to lock the two elements together.

11. Claims 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over LaSalle (U.S. Patent 5,976,147) in view of Goss (U.S. Patent 5,639,113).

LaSalle discloses the invention as claimed except for the first coupler being a bore and the second coupler being a pin received within the bore, wherein the bore defines an internal groove that receives an o-ring engaging the pin.

LaSalle discloses a device as discussed above comprising a first coupler and a second coupler, wherein the first coupler defines a pin like element and the second coupler is an aperture/bore to receive the first coupler to lock the elements of the device together. Goss teaches a device comprising a first coupler (12) defining a pin having a resilient o-ring (28) engaged with the first coupler and a second coupler defining a bore including an internal groove (19) in order to lock the elements of the device together. Because both LaSalle and Goss disclose coupling elements for locking elements of a device together, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute one set of coupling element for the other in order to achieve the predictable results of locking the elements of the device together.

Regarding the first coupler being a bore and the second coupler being a pin, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of LaSalle as modified by Goss wherein the first

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coupler is a bore and the second couple is a pin received within the bore, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

12. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over LaSalle (U.S. Patent 5,976,147).

LaSalle discloses the invention as claimed except for the first coupler being a bore and the second coupler being a pin received within the bore. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of LaSalle wherein the first coupler is a bore and the second couple is a pin received within the bore, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

13. Claims 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over LaSalle (U.S. Patent 5,976,147) in view of Goss (U.S. Patent 5,639,113).

LaSalle discloses a device comprising an instrument (12 and 18), an augment (20), and an intramedullary pin (16). The instrument includes a positioning member (18) defining a femur facing side and a tibia facing side, wherein the instrument includes a first coupler (elements 88, 90, 92, 94, etc.; see Figure 6) defining a pin like structure, a guide slot (the bore in the middle of element 12 that receives element 16) that receives the intramedullary pin, a handle extending from the positioning member (column 6 lines 33-36). The augment includes a second coupler (124) defining a bore that cooperates with the first coupler to fix the augment to the positioning member (see column 7 lines

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15-24). LaSalle discloses the invention as claimed except for the first coupler being a bore and the second coupler being a pin received within the bore, wherein the bore defines an internal groove that receives an o-ring engaging the pin.

LaSalle discloses a device as discussed above comprising a first coupler and a second coupler, wherein the first coupler defines a pin like element and the second coupler is an aperture/bore to receive the first coupler to lock the elements of the device together. Goss teaches a device comprising a first coupler (12) defining a pin having a resilient o-ring (28) engaged with the first coupler and a second coupler defining a bore including an internal groove (19) in order to lock the elements of the device together. Because both LaSalle and Goss disclose coupling elements for locking elements of a device together, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute one set of coupling element for the other in order to achieve the predictable results of locking the elements of the device together.

Regarding the first coupler being a bore and the second coupler being a pin, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of LaSalle as modified by Goss wherein the first coupler is a bore and the second couple is a pin received within the bore, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

Allowable Subject Matter

14. Claims 35 and 36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the

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limitations of the base claim and any intervening claims and to if written to overcome the rejection of the claims under 35 U.S.C. 101 as discussed above.

Response to Arguments

15. Applicant's arguments with respect to claims 24-43 have been considered but are moot in view of the new ground(s) of rejection. The applicant's arguments directed to the rejection of claims 24-43 under 35 U.S.C. 101 has been discussed above. The examiner has provided new grounds of rejection as necessitated by the amendment making this office action **FINAL**.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examiner felt were relevant to the application.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is (571)272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas Woodall/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
Unit 3775